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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/183,824 10/30/98 RAJU

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EXAMINER

HM22/0620

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ART UNIT

PAPER NUMBER

1644

10

DATE MAILED:

06/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/183,824

Applicant(s)

Raju

Examiner
Ron Schwadron, Ph.D.

Group Art Unit
1644



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-44 is/are pending in the application.
- Of the above, claim(s) 1-9, 17-35, 37, 39-41, and 43 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 10-16, 36, 38, 42, and 44 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election without traverse of Group B, claims 10-16,36,38,42,44 in Paper No. 9 is acknowledged.
2. Claims 1-7,20,35,37,39,41,43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
3. Claims 10-16,36,38,42,44 are under consideration.
4. The information disclosure statement filed 7/7/1999 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Said IDS was filed after the Office Action mailed 6/24/99. The information disclosure statement filed fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e) and/or it fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 10-16,36,38,42,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paulson et al. (US Patent 5,047,335) in view of Weitzhandler et al and prior art disclosed in the specification (page 16).

Paulson et al. teach methods of producing proteins with a particular glycosylation pattern and said proteins (see columns 2 and 3). Paulson et al. teach that proteins with

altered glycosylation patterns are useful for a variety of purposes including diagnostic and research purposes (see column 3). Paulson et al. do not specifically teach the claimed composition of a glycoprotein containing a CH2 domain containing G-2 oligosaccharide which is substantially free of CH2 domain containing other oligosaccharides. Weitzhandler et al. teach that antibodies contain a CH2 domain and that oligosaccharides are attached at said CH2 domain (see page 1670). Weitzhandler et al. teach enzymatic digestion can be used to release various oligosaccharide molecules from antibodies (see page 1670). Weitzhandler et al. teach that treatment with PNGase followed by treatment with Jack bean enzyme would result in conversion of structure 1 depicted in figure 2 into a G-2 oligosaccharide (see page 1674, second column). The specification discloses that a variety of therapeutically useful antiCD20 antibodies were known in the art (see cited references, specification, page 16). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Paulson et al. teach that proteins with altered glycosylation patterns are useful for a variety of purposes including diagnostic and research purposes while Weitzhandler et al teach that treatment with PNGase followed by treatment with Jack bean enzyme would result in G-2 containing oligosaccharide antibody molecules. One of ordinary skill in the art would have been motivated to do the aforementioned to created altered oligosaccharide versions of known therapeutically useful antibodies such as antiCD20 antibodies in order to assess the role of oligosaccharide function in the therapeutic effect seen when said antibody was administered. The G-2 containing antibody would be administered in the form of a pharmaceutical composition.


6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-

4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644


RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 1600